UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,663	01/18/2002	Vernon M. Ingram	M00656/70071 (JRV)	3098

23628 7590 06/27/2005

WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,663	INGRAM ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,34 and 49* is/are pending in the application.

4a) Of the above claim(s) *34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29* is/are rejected.

7)☒ Claim(s) *49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.00

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 16, 2005 has been entered.

2. Applicant's response and submitted IDS dated March 16, 2005 is acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 29, 34 and 49 are currently pending.

Claims 29 and 49 are under consideration.

Claim 34 is withdrawn from consideration as being directed to a nonelected invention.

Election/Restriction

3. Applicant's election with traverse of Group V (claim 29: composition comprising an inhibitor of neural membrane depolarization and a compound that decrease neuronal calcium influx) and i. DAPH1 (4,5-dianilinophthalimide) as a compound species that decreases neuronal membrane depolarization of neuronal cells caused by aggregated beta-amyloid protein degradation products and ii. 2,3-dihydroxy-nitro-7-sulfamoyl-benzo[f]quinoxaline (NBQX) as the compound that decreases neuronal calcium influx in the correspondences dated 10/31/03 and 1/15/04, respectively, is again acknowledged.

4. Claim 34 is withdrawn from consideration as being directed to a nonelected invention. It is noted that, in accordance with U.S. practice, the Examiner will *consider rejoinder of* a method of use (e.g. claim 34) which is commensurate in scope to allowed subject matter pursuant to MPEP 821.04 Rejoinder.

Allowable Subject Matter

5. Claim 49 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Withdrawn Objection (s) and/or Rejection (s)

Applicant's arguments directed to the obviousness rejections of claim 29 and 49 as being obvious under 35 U.S.C. 103(a) over Buxbaum Pat No. 5,385,915 (1/95) alone or further in view of Ingram et al. PG PUB US 2003/0114510A1 (6/03) as evidence of inherency (item 8 in the prior office action) and further in view of WO 98/30229 (7/98) or Sharpe were found persuasive. Additionally, the teaching of tyrphostin in Buxbaum would not provide sufficient motivation to one of ordinary skill in the art to select DAPHI from the Sharpe reference due to the nonalaogous structure of tyrphosin and DAPHI and the large number of structurally unrelated Sharpe compounds drawn to different generics disclosed in the Sharpe reference.

Outstanding Objection(s) and/or Rejection (s)

6. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (lack of written description).

It is first noted that written description is legally distinct from enablement: " Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention" See 1242 OG 169 (January 30, 2001) citing *University of California v. Eli Lilly & Co*

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

The *Lilly* court sets forth a two part test for written description: A description of a genus of cDNA's may be achieved by means of a recitation of:

1. a representative number of cDNA;s, defined by nucleotide sequence, falling within the scope of the genus Or

2. of a recitation of structural features common to the members of the genus.

See *Regents of the University of California v. Eli Lilly & Co.* 119 F.3d 1559 (Fed. Cir. 1997) at 1569.

The present claim is directed to: A composition comprising:

a. DAPH1 (4,5-dianilinophthalimide) AND

b. one or more compounds that "*decrease neuronal calcium influx caused by beta amyloid protein degradation products*"..

In support thereof of item b. above, the specification merely provides a handful of compounds corresponding to item b. (e.g. Non-NMDA channel antagonist compounds, decoy peptides) in which functional/mechanistic properties are not correlative to a single compound core structure. See e.g. *Ingram et al.* PG PUB US 2003/0114510A1 (6/03) (of present application) at pages 1-7.

In the present instance, neither the specification nor the claims provide:

1. A recitation of structural features common to the members of the "genera" corresponding

to "*compounds that decrease neuronal calcium influx caused by beta amyloid protein degradation products" OR*

2. a representative number of compounds that decrease neuronal calcium influx caused by aggregated beta-amyloid protein degradation products..

Accordingly, neither the specification nor claims demonstrate possession of the presently claimed function/mechanistic claimed generics.

Discussion

Applicant's arguments directed to the above written description rejection were considered but deemed nonpersuasive for the following reasons.

Applicant first argues that the Lilly criteria are pertinent only to cDNA'S not to non-DNA compounds e.g. calcium influx caused by aggregated amyloid.

This argument is not persuasive since both the MPEP and relevant caselaw (e.g. University of Rochesterj therein have applied written description and the Lilly analysis to non-DNA compounds. See e.g. Guidelines for Examination of Patent Applications Under the 35 USC 1 12, first paragraph, "Written Description' Requirement" published in 1242 0G 168-178 (January 30, 2001); and Univ. Of Rochester v G. D. Searle and Co., 69 USPQZd 1886 (CAFC Feb. 13, 2004).

Applicant further argues that structure or representative examples is not the only way to satisfy written description and that decoy peptides and non-NMDA channel antagonists are well known in the art.

This argument was considered but deemed nonpersuasive for the following reasons.

Initially it is noted that there is no *per se* test for satisfying written description; but the MPEP and recited case law provide an analysis (which the Examiner employs) for

determining whether written description has been met.

Secondly, whether non-NMDA channel antagonists or decoy peptides are known in the art is not the proper inquiry. The issue is whether the specification has provided a sufficient showing to demonstrate possession of the presently claimed invention.

In this respect, Applicant argues that the specification provides an adequate written description of compounds that decrease calcium influx of neuronal cells caused by aggregated β-amyloid (Aβ) protein degradation products since the specification describes:

a. Decoy peptides (e.g. pp. 9,16),

b. A number of non-NMDA antagonists (see pp 16-17), and

c. Other antagonists of calcium channels (see page 16) including NMDA antagonists such as DL-APS (see Example 1, p. 30);

which, although structurally different, would nevertheless, given the knowledge in the art of these compounds, be viewed as representative of compounds that decrease calcium influx of neuronal cells caused by aggregated β-amyloid (Aβ) protein degradation products.

This argument was considered but deemed nonpersuasive for the following reasons.

As recognized by the courts, "[T]he written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant, identifying characteristics ... i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed

correlation between function and structure, or some combination of such characteristics." *Enzo Biochem. Inc. V. Gen-probe Inc.* 296 F.3d 1316,1324, 63 USPQZd 1609,1613 (Fed. Cir. 2002).

In the present instance, Applicant's claimed composition comprising compounds that decrease calcium influx of neuronal cells caused by aggregated beta-amyloid (Ag) protein degradation products represents a vague ' functional description' 1 which lacks any structural feature (e.g. core structure) common to compounds that decrease calcium influx; nor is there sufficiently detailed, relevant, identifying characteristics ... i.e. complete or partial structure, other physical and/or chemical propedies to provide an adequate written description. Even though the specification provides specific examples of 'decoy peptides' and an NMDA antagonist (e.g. DL-AP5) these compounds are structurally distinct and do not establish a known or disclosed correlation between function and structure sufficient to provide adequate written description', nor do these disclosed compounds provide functional/mechanistic properties which are correlative to a single compound core structure(s).

1 The claimed phrase "a non-steroidal compound that selectively inhibits activity of the PGNSQ gene product" was labeled by the CAFC as a "vague functional description". See *University of Rochester v. G.D. Sear/e & Co.*, 69 USPQ 2d 1886,1895 (CAFC 2004).

Accordingly, as pointed out in the rejection above, applicant's claim to a 'vague functional description' and the limited numbers of specification examples fail to provide:

1. A recitation of structural features common to the members of the 'genera'

corresponding to 'compounds that decrease neuronal calcium influx by beta amyloid protein degradation products' OR

2. A representative number of compounds that decrease neuronal calcium influx caused by aggregated beta-amyloid protein degradation products.

Thus, neither the specification nor claims provides an adequate written description of compounds that decrease calcium influx of neuronal cells caused by aggregated β-amyloid (Aβ) protein degradation products as presently claimed.

Accordingly, the above written description rejection is hereby maintained.

Conclusion

7. This is a RCE of applicant's earlier Application No. 10/051,663. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
June 21, 2005